

# To Err Really is Human: Misunderstanding Medication Labels



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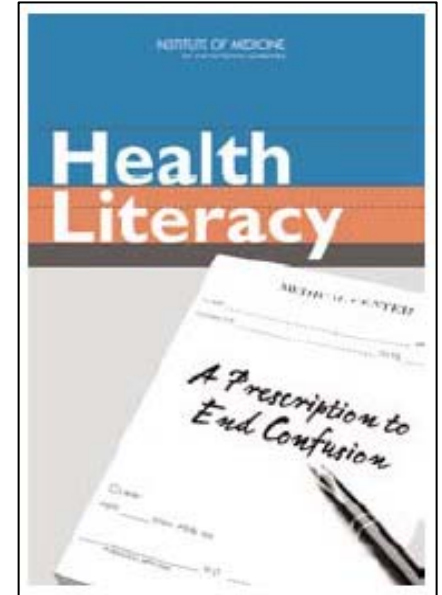
# Overview

- What is health literacy?
- What is a medication label?
- What do we know about health literacy and medication labels?
- How can we improve OTC drug labels?



# IOM Report on Health Literacy

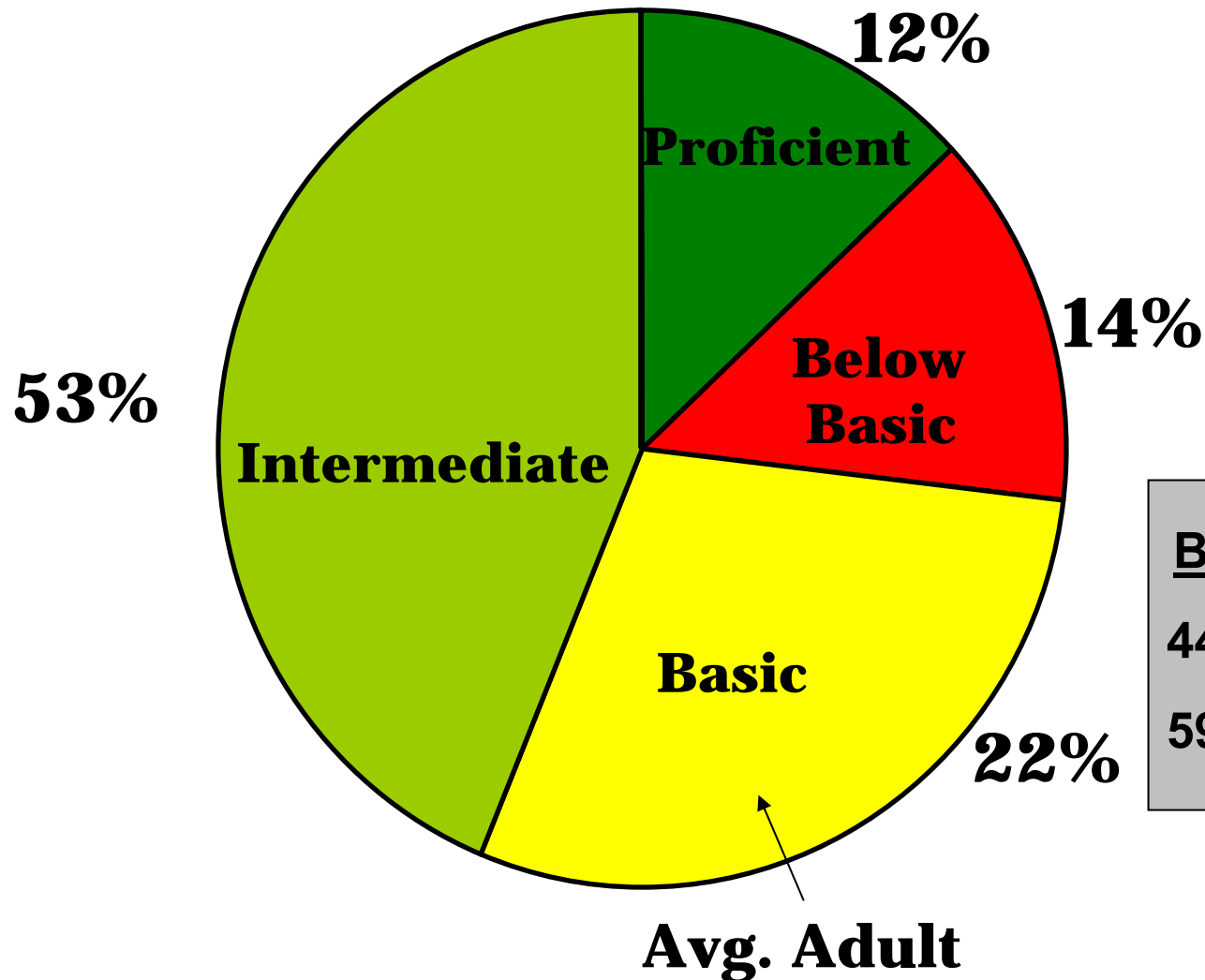
- **90 million** adults have trouble understanding and acting on health information
- Complex text must be simplified and attention paid to culture and language



## Healthy People 2010

- Improve health communication/health literacy

# Health Literacy of America's Adults



## Basic or Below Basic

44% of H.S. Grads

59% of Adults  $\geq 65$



- Cannot understand how to take Rx medicines based on common label instructions
- Cannot identify 3 substances that interact with an OTC drug based on the label





**U.S. high school dropout rate is 30%**

# Video

**You can't tell by looking**

# Medication Label

## A System of Information

- **Primary container labels**  
(state regulated, FDA requirements)
- **Auxiliary Labels (Warning Labels)**  
(industry-generated, not standardized)
- **Consumer Medication Information (CMI)**  
(industry-generated)
- **Medication Guides-Prescription only for providers**  
(28 developed by FDA)
- **Patient Package Information (PPI)-for provider**  
(written by manufacturer approved by FDA)



Drug

TRANSDERM SCOP<sup>®</sup>



PPI

Transderm Scop

Transdermal Therapeutic System

Auxiliary Label

Primary Container Label











# **FDA and OTC Drug Labels**

## **1966-Fair Packaging and Labeling Act**

All consumer products in interstate commerce to be honestly and informatively labeled

## **1999-Creation of Drug Facts Label for OTC's**

Required standard format for all OTC drug labels to give easy-to-find information

# WHAT'S ON THE LABEL

All nonprescription, over-the-counter (OTC) medicine labels have detailed usage and warning information so consumers can properly choose and use the products.

Below is an example of what the new OTC medicine label looks like.

## ACTIVE INGREDIENT

Therapeutic substance in product; amount of active ingredient per unit

## USES

Symptoms or diseases the product will treat or prevent

## WARNINGS

When not to use the product; conditions that may require advice from a doctor before taking the product; possible interactions or side effects; when to stop taking the product and when to contact a doctor; if you are pregnant or breastfeeding, seek guidance from a health care professional; keep product out of children's reach

### Drug Facts

Active ingredient (in each tablet)

Chlorpheniramine maleate 4 mg

Use: temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, runny nose, itchy, watery eyes, itchy throat

Warnings: ask a doctor before use if you have asthma, a breathing problem such as emphysema or chronic bronchitis, trouble urinating due to an enlarged prostate gland, ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product: you may get drowsy, avoid alcoholic drinks, alcohol, sedatives, and tranquilizers may increase drowsiness, be careful when driving a motor vehicle or operating machinery, avoid grapefruit juice, especially in children

Keep out of reach of children. In case of overdose, call a poison control center right away.

Directions: adults and children 12 years and over: take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours; children 6 years to under 12 years: take 1 or 2 tablets every 4 to 6 hours; not more than 2 tablets in 24 hours; children under 6 years: ask a doctor

Other information: store at 20-25°C (68-77°F); protect from excessive moisture

Inactive ingredients: D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol

## INACTIVE INGREDIENTS

Substances such as colors or flavors

*The Drug Facts labeling requirements do not apply to dietary supplements, which are regulated as food products, and are labeled with a Supplement Facts panel.*

## PURPOSE

Product action or category (such as an antihistamine, antacid, or cough suppressant)

## DIRECTIONS

Specific age categories, how much to take, how to take, and how often and how long to take

## OTHER INFORMATION

How to store the product properly and required information about certain ingredients (such as the amount of calcium, potassium, or sodium the product contains)



For more information visit: [www.fda.gov/cder](http://www.fda.gov/cder) or call 1-888-INFO-FDA  
U.S. Department of Health and Human Services  
Food and Drug Administration





# OTC Drug Facts

**Do not use if the individual blister unit is open or torn. Read Package Insert before use.**

Drug Facts	Purpose
<b>Active ingredient (in each tablet)</b> Famotidine 20 mg	Acid reducer
<b>Uses</b> • relieves heartburn associated with acid indigestion and sour stomach • prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages	
<b>Warnings</b> <b>Allergy alert:</b> Do not use if you are allergic to famotidine or other acid reducers <b>Do not use</b> • if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. • if you have kidney disease, except under the advice and supervision of a doctor • with other acid reducers <b>Ask a doctor before use if you have</b> • had heartburn over 3 months. This may be a sign of a more serious condition. • heartburn with lightheadedness, sweating, or dizziness • chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness • frequent chest pain • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain	
<b>Drug Facts (continued)</b> <b>Stop use and ask a doctor if</b> • your heartburn continues or worsens • you need to take this product for more than 14 days <b>If pregnant or breast-feeding, ask a health professional before use.</b> <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. <b>Directions</b> • adults and children 12 years and over: • to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew. • to prevent symptoms, swallow 1 tablet with a glass of water at any time from 10 to 60 minutes before eating food or drinking beverages that cause heartburn • do not use more than 2 tablets in 24 hours • children under 12 years: ask a doctor <b>Other information</b> • read the directions and warnings before use • keep the carton and package insert. They contain important information. • store at 20° - 30° C (68° - 86° F) • protect from moisture <b>Inactive ingredients</b> carnauba wax, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, talc, titanium dioxide <b>Questions or comments?</b> 1-800-755-4000 (English) or 1-800-466-6746 (Spanish)	

08735180

**Drug Facts**

Active ingredient (in each tablet)	Purpose
Ranitidine 75 mg (as ranitidine hydrochloride USP, 84 mg)	Acid reducer
<b>Uses</b> • relieves heartburn associated with acid indigestion and sour stomach • prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages	
<b>Warnings</b> <b>Allergy alert:</b> Do not use if you are allergic to ranitidine or other acid reducers <b>Do not use</b> • if you have trouble swallowing • with other acid reducers <b>Stop use and ask a doctor if</b> • stomach pain continues • you need to take this product for more than 14 days <b>If pregnant or breast-feeding, ask a health professional before use.</b> <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. <b>Directions</b> • adults and children 12 years and over: • to relieve symptoms, swallow 1 tablet with a glass of water • to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn • can be used up to twice daily (up to 2 tablets in 24 hours) • children under 12 years: ask a doctor <b>Other information</b> • this product is sodium and sugar free • do not use if the carton or individual blister unit is open or torn • avoid excessive heat or humidity • store at 20° - 25° C (68° - 77° F) (See USP Controlled Room Temperature). <b>Inactive ingredients</b> castor oil, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, red iron oxide, talc, titanium dioxide May contain edible ink. <b>Read the directions, consumer information leaflet and warnings before use.</b> <b>Keep the carton. It contains important information.</b> If you have any questions of a medical nature, please contact your Pharmacist, Doctor or Health Care Provider.	

**Drug Facts** Read the directions and warnings before taking this product. KEEP THE PRODUCT INFORMATION SHEET. IT CONTAINS IMPORTANT INFORMATION.

Active ingredient (in each tablet)	Purpose
Cimetidine 200 mg	Acid reducer
<b>Uses</b> • relieves heartburn associated with acid indigestion and sour stomach • prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages	
<b>Warnings</b> <b>Allergy alert:</b> Do not use if you are allergic to cimetidine or other acid reducers <b>Do not use</b> • if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. • with other acid reducers <b>Ask a doctor before use if you have</b> • frequent chest pain • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain • had heartburn over 3 months. This may be a sign of a more serious condition. • heartburn with lightheadedness, sweating or dizziness • chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness <b>Ask a doctor or pharmacist before use if you are taking</b> • theophylline (oral asthma medicine) • warfarin (blood thinning medicine) • phenytoin (seizure medicine) If you are not sure you are taking one of these medicines, talk to your doctor or pharmacist. <b>Stop use and ask a doctor if</b> • your heartburn continues or worsens • stomach pain continues • you need to take this product for more than 14 days <b>If pregnant or breast-feeding, ask a health professional before use.</b> <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. <b>Directions</b> • adults and children 12 years and over: • to relieve symptoms, swallow 1 tablet with a glass of water • to prevent symptoms, swallow 1 tablet with a glass of water right before or any time up to 30 minutes before eating food or drinking beverages that cause heartburn • do not take more than 2 tablets in 24 hours • children under 12 years: ask a doctor <b>Other information</b> • store at 15-30° C (59-86° F) <b>Inactive ingredients</b> cellulose, corn starch, hypromellose, magnesium stearate, polyethylene glycol, polyorbite 80, povidone, sodium lauryl sulfate, sodium starch glycolate, titanium dioxide <b>Questions or comments?</b> call toll-free 1-800-482-4394 (English/Spanish) weekdays 3 0766-5016-30 9	



# **PPI for OTCs**

**FDA requires insert for limited number of OTC drugs**

- Vaginal sponges
- Vaginal anti-fungals
- H2 blockers
- Nicotine replacements



The use of this individual bottle will be found on box.

**WHAT YOU SHOULD KNOW ABOUT:**

**MAXIMUM STRENGTH Pepcid AC**  
Acid Reducer Famotidine Tablets 20 mg

**A non-prescription stomach medicine**

**How to use MAXIMUM STRENGTH PEPCID® AC**

**Excess acid: a burning problem**

**How do Ranitidine Tablets work?**

**Additional tips for managing heartburn**

**What you should know about Ranitidine Tablets 75 mg Acid Reducer**

**What are Ranitidine Tablets?**

**What symptoms do Ranitidine Tablets treat and prevent?**

**How should I take Ranitidine Tablets?**

**How do Ranitidine Tablets work?**

**Additional tips for managing heartburn**

**Tagamet HB 200**  
Cimetidine Tablets 200 mg/Acid Reducer

**For Heartburn**

**SAVE \$2 NOW**  
on any Tagamet HB 200 (10 or 30 tablets)

**AND... SAVE \$2 LATER**

**How often do you use over-the-counter heartburn medicine?**

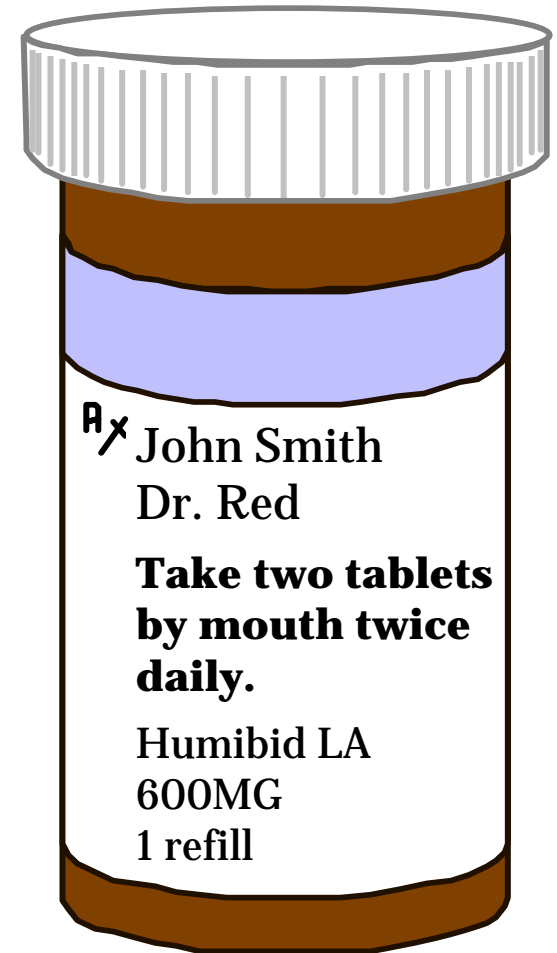
**How often do you use prescription heartburn medicine?**

**How often do you use over-the-counter heartburn medicine?**

**How often do you use prescription heartburn medicine?**

# Hidden Problems with Medication Labels

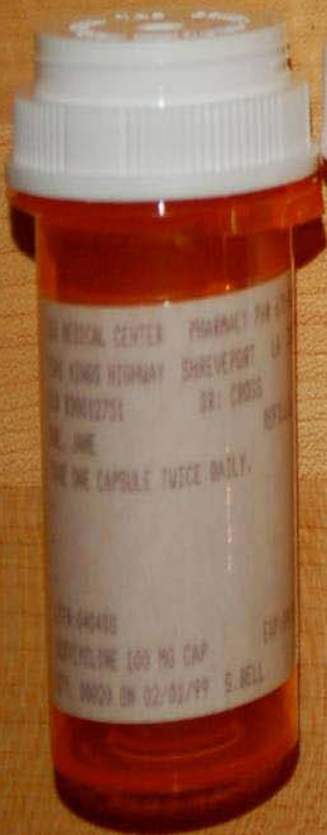
- More than 10,000 Rx and 300,000 OTC in U.S. market
- Over 1/3 of U.S. adults cannot understand common dosing instructions on a pill bottle
- Poor understanding is a source of medication error and an issue of safety
- Simple label instructions are not always clear or understood



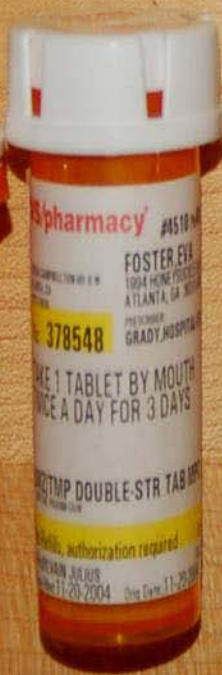
# Video

**Understanding medication labels: An issue  
of safety**





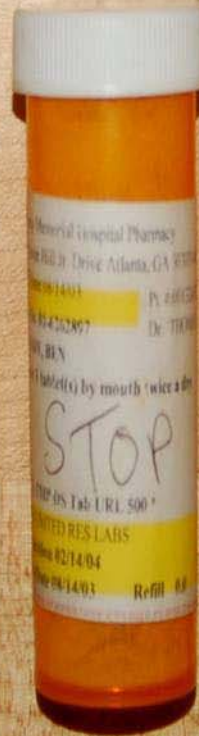
One  
capsule  
twice daily



One  
tablet  
by  
mouth  
twice a  
day for  
3 days



One  
tablet  
two  
times  
a day



One  
tablet by  
mouth  
twice a  
day



Tomar  
1tab XLA  
boca  
vez dia X7  
dias luego  
do XLA  
boca X7  
dias



Take one  
by mouth  
3? Times  
a day



Take as  
directed

# “How would you take this medicine?”

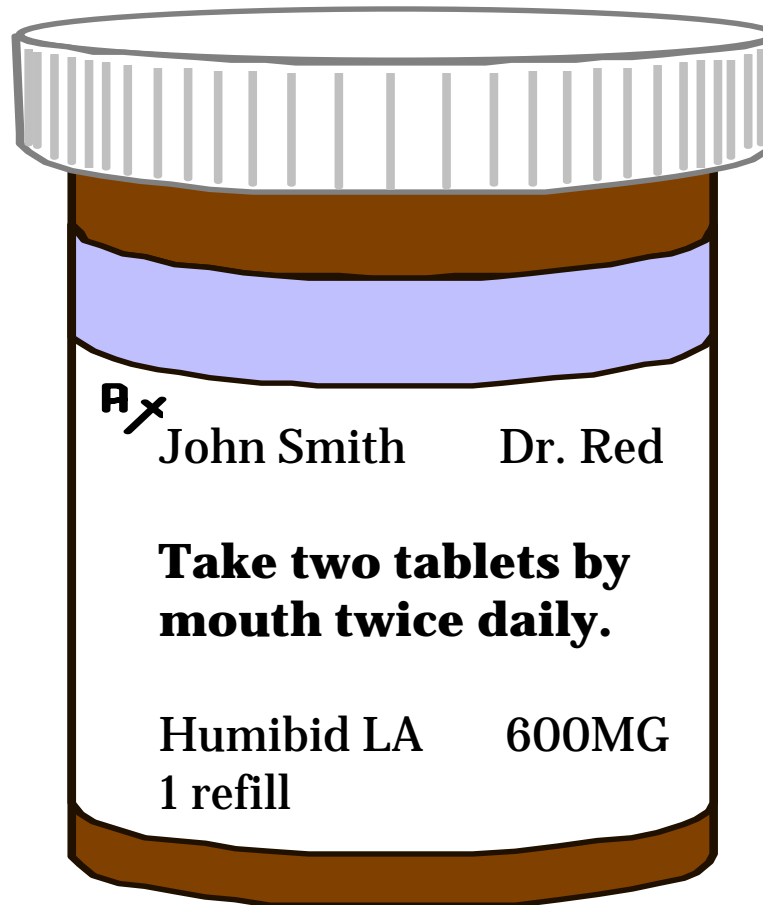
395 primary care patients in 3 states



- **46%** did not understand instructions  $\geq 1$  labels
- **38%** with adequate literacy missed at least 1 label

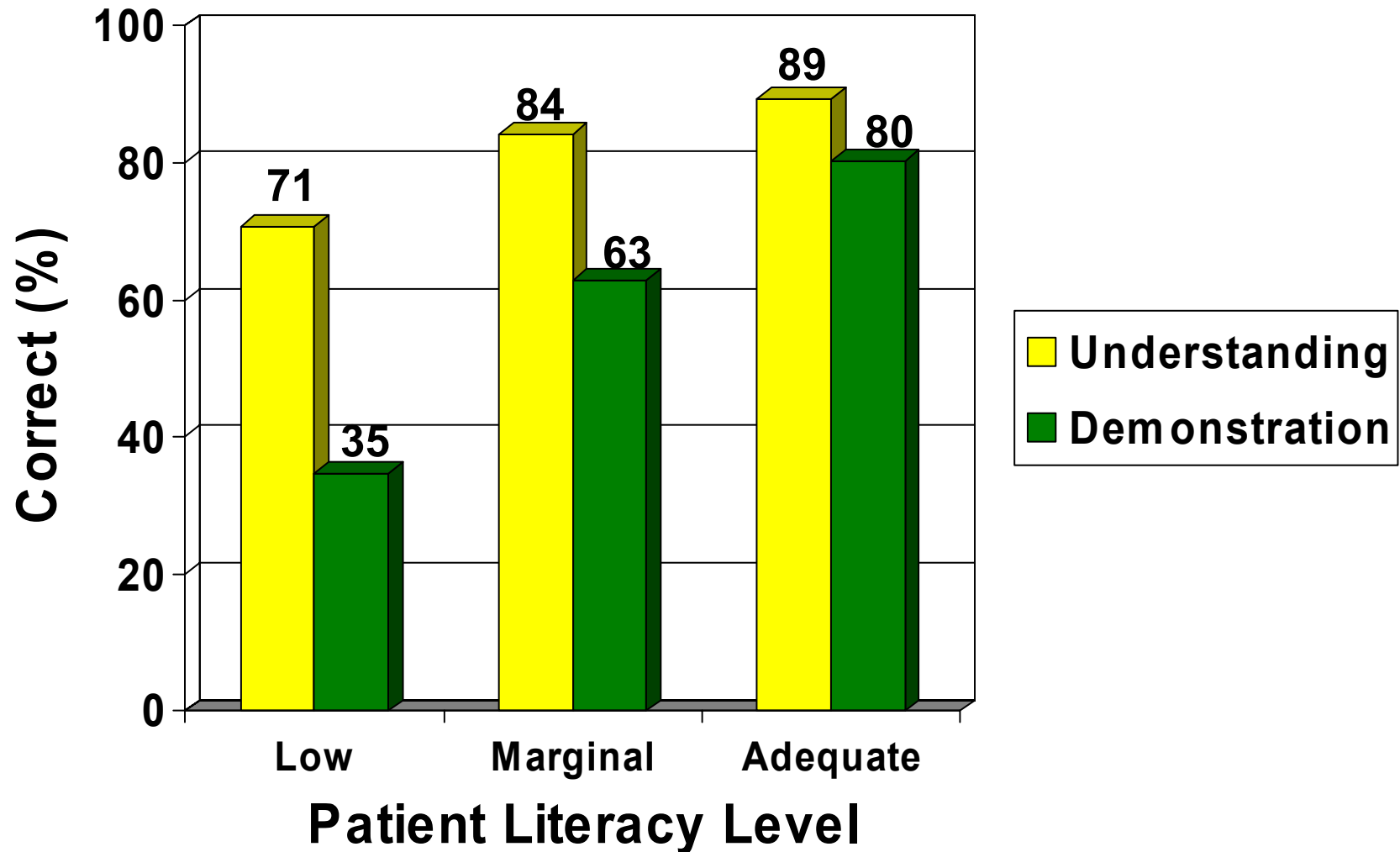


# “Show Me How Many Pills You Would Take in 1 Day”



# Rates of Correct Understanding vs. Demonstration

## “Take Two Tablets by Mouth Twice Daily”



# “What does this warning label mean?”



- 9 pharmacists and 5 physicians choose 8 commonly used warning labels
- 253 public health primary care patients were shown bottles one at a time

# Simple familiar wording understood by most patients



84%

(1<sup>st</sup> gd.)

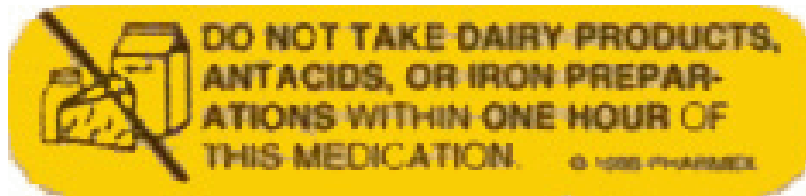
# More complex message limited comprehension



59%

(10<sup>th</sup>-12<sup>th</sup> gd.)

# Unfamiliar multi-step instructions rarely understood




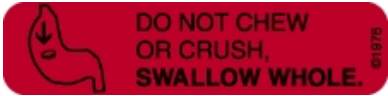


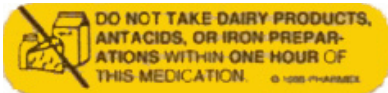
8%

(12<sup>th</sup>-13<sup>th</sup> gd. level)



# Comprehension Increased with Patient Literacy Level

\* p<.0001, † p<.05

	<u>&lt;6</u>	<u>7-8</u>	<u>&gt;9</u>
 79%	79%	86%	88% †
 35%	35%	66%	78% *
 8%	8%	64%	82% *
 8%	8%	18%	23% *
 0%	0%	6%	15% *

In multivariant analysis only literacy and age predicted comprehension.

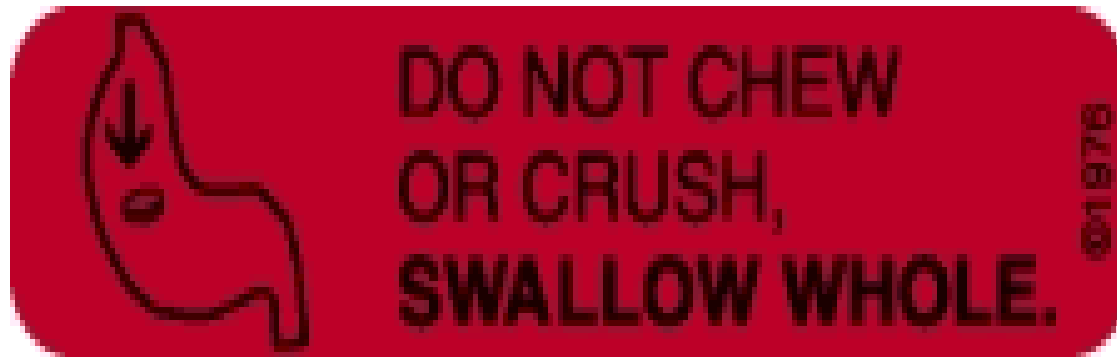
Patients with low literacy (< 6th gd.) 3X more likely to incorrectly interpret warning labels.

# What does this picture mean?



- “Someone swallowed a nickel”
- “Indigestion”
- “Bladder”
- “Looks like a ghost- Casper”

# Does adding the words help?



- “Chew pill and crush before swallowing”
- “Chew it up so it will dissolve, don’t swallow whole or you might choke”
- “Just for your stomach”

# What does this picture mean?



- “Somebody is dizzy”
- “Don’t touch this stuff”
- “Take anywhere”
- “Chills or shaking”
- “Someone is having an experience with God”

# Does adding the words help?



- “Use extreme caution in how you take it”
- “Medicine will make you feel dizzy”
- “Take only if you need it”

# Labels-short and simple, but not clear to many



Many need more specific, concrete information.

- *“What time do I take them?”*
- *“Do I take every 4 or 6 hours?”*
- *“Do I take them with food?”*
- *“What if I can’t afford a whole bottle?”*



# Conclusions

- **Health literacy=skills + task complexity**
  - U.S. skill level not improving
  - “ordinary” adult lacks adequate skills
  - task complexity (labels) need improvement
- **Research findings:**
  - simple does not equal clear
  - current warnings confusing
  - limited evidence of “best practices” for labels

# How to Improve OTC Labels?

- Find the best way to say it (*Clarification*)
- Always say it the same way (*Standardization*)
- Don't say more than you need to (*Evidence*)
- Make up your mind about language (*Spanish?*)
- Warn with an icon
- PPI's – Information for advertising?